

In the Claims

1. (currently amended) An orally administrable abuse-deterrent pharmaceutical composition comprising a therapeutically effective amount of microparticles consisting of

(a) ~~a therapeutically effective amount of~~ a lipophilic drug or lipophilic derivative of a drug prone to abuse, and

(b) ~~a formulation comprising one or more~~ carrier materials selected from the group consisting of fats, fatty substances, waxes, wax-like substances and mixtures thereof,

wherein the drug is dispersed within the one or more carrier materials, ~~which prevents the immediate and the~~ release of a portion of incorporated drug ~~is retarded~~ when the physical integrity of the composition is compromised and ~~the resulting material is~~ compromised composition is exposed to water.

2. (currently amended) An orally administrable abuse-deterrent pharmaceutical composition comprising a therapeutically effective amount of microparticles consisting of a lipophilic derivative of a drug prone to abuse dispersed within one or more carrier materials which are either slowly soluble in water or insoluble in water, wherein the release of a portion of incorporated drug is retarded when the physical integrity of the composition is compromised and the compromised composition is exposed to water.

3. (previously presented) The composition of Claim 1 or 2, wherein the composition is a controlled-release pharmaceutical composition.

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4. (currently amended) The composition of claim 1 or 2, wherein release of a portion of incorporated the drug is substantially retarded dispersed with the carrier materials which prevents the immediate release of a substantial portion of incorporated drug when the physical integrity of the composition is compromised and the resulting material is exposed to water.

5. (currently amended) The composition of Claim 1 or 2 [[4]], wherein the portion of the drug released immediately when the physical integrity of the composition is compromised is less than 80% of the total amount of drug incorporated into the formulation.

6. (currently amended) The composition of Claim 1 or 2, wherein the ~~composition prevents the immediate~~ release of a ~~substantial~~ portion of incorporated drug is retarded when the physical integrity of the composition is compromised and the ~~resulting material is~~ compromised composition is exposed to an aqueous medium.

7. (currently amended) The composition of Claim 6, wherein the portion of the drug released immediately when the physical integrity of the composition is compromised is less than 80% of the total amount of the drug incorporated into the composition.

8. (original) The composition of Claim 1 wherein the drug prone to abuse is selected from the group consisting of 1-phenylcyclohexylamine, 1-piperidinocyclohexanecarbonitrile, alfentanil, alphacetylmethadol, alphaprodine, alprazolam, amobarbital, amphetamine, anileridine, apomorphine, aprobarbital, barbital, barbituric acid derivative, bemidone, benzoylcegonine, benzphetamine, betacetylmethadol, betaprodine, bezitramide, bromazepam, buprenorphine, butabarbital, butalbital, butorphanol, camazepam, cathine, chloral,

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chlordiazepoxide, clobazam, clonazepam, clorazepate, clotiazepam, cloxazolam, cocaine, codeine, chlorphentermine, delorazepam, dexfenfluramine, dextromoramide, dextropropoxyphen, dezocine, diazepam, diethylpropion, difenoxin, dihydrocodeine, dihydromorphine, dioxaphentyl butyrate, dipanone, diphenoxylate, diprenorphine, ecgonine, enadoline, eptazocine, estazolam, ethoheptazine, ethyl loflazepate, ethylmorphine, etorphine, femproporex, fencamfamin, fenfluramine, fentanyl, fludiazepam, flunitrazepam, flurazepam, glutethimide, halazepam, haloxazolam, hexalgon, hydrocodone, hydromorphone, isomethadone, hydrocodone, ketamine, ketazolam, ketobemidone, levanone, levoalphacetylmethadol, levomethadone, levomethadyl acetate, levomethorphan, levorphanol, lofentanil, loperamide, loprazolam, lorazepam, lormetazepam, lysergic acid, lysergic acid amide, mazindol, medazepam, mefenorex, meperidine, meptazinol, metazocine, methadone, methamphetamine, methohexital, methotrimeprazine, methyl dihydromorphinone, methylphenidate, methylphenobarbital, metopon, morphine, nabilone, nalbuphine, nalbupine, nalorphine, narceine, nefopam, nicomorphine, nimetazepam, nitrazepam, nordiazepam, normethadone, normorphine, oxazepam, oxazolam, oxycodone, oxymorphone, pentazocine, pentobarbital, phenadoxone, phenazocine, phencyclidine, phendimetrazine, phenmetrazine, pheneridine, piminodine, prodilidine, properidine, propoxyphene, racemethorphan, racemorphan, racemoramide, remifentanyl, secobarbital, sufentanil, talbutal, thebaine, thiamylal, thiopental, tramadol, trimeperidine, vinbarbital, allobarbitone, alprazolam, amylobarbitone, aprobarbital, barbital, barbitone, benzphetamine, brallobarbitol, bromazepam, brotizolam, buspirone, butalbital, butobarbitone,

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butorphanol, camazepam, captodiamine, carbromal, carfentanil, carpipramine, cathine, chloral, chloral betaine, chloral hydrate, chloralose, chlordiazepoxide, chlorhexadol, chlormethiazole edisylate, chlormezanone, cinolazepam, clobazam, potassium clorazepate, clotiazepam, cloxazolam, cyclobarbitone, delorazepam, dexfenfluramine, diazepam, diethylpropion, difebarbamate, difenoxin, enciprazine, estazolam, ethyl loflazepate, etizolam, febarbamate, fencamfamin, fenfluramine, fenproporex, fluanisone, fludiazepam, flunitraam, flunitrazepam, flurazepam, flutoprazepam, gepirone, glutethimide, halazepam, haloxazolam, hexobarbitone, ibomal, ipsapirone, ketazolam, lorazepam, lorazepam mesylate, lorazepam, lormetazepam, mazindol, mebutamate, medazepam, mefenorex, mephobarbital, meprobamate, metaclozepam, methaqualone, methohexital, methylpentynol, methylphenobarbital, midazolam, milazepam, morphine, nimetazepam, nitrazepam, nordiazepam, oxazepam, oxazolam, paraldehyde, pemoline, pentobarbitone, pentazocine, pentobarbital, phencyclidine, phenobarbital, phendimetrazine, phenmetrazine, phenprobamate, phentermine, phenylacetone, pinazepam, pipradol, prazepam, proxibarbal, quazepam, quinalbarbitone, secobarbital, secbutobarbitone, sibutramine, temazepam, tetrazepam, triazolam, triclofos, zalepan, zaleplon, zolazepam, zolpidem, and zopiclone.

9. (previously presented) The composition of Claim 1 or 2, wherein the lipophilic derivative of a drug is a free base or a free acid of the drug.

10. (previously presented) The composition of Claim 1 or 2, wherein the lipophilic derivative of a drug is a salt comprising the ionized drug and a lipophilic counter-ion.

11. (previously presented) The composition of Claim 1 or 2, wherein the lipophilic derivative of a drug is a complex comprising one or more components selected from the group consisting of drug molecules, metal cations, and lipophilic counter-ions.

12. (previously presented) The composition of Claim 1 or 2, wherein the lipophilic derivative of a drug is a complex comprising one or more components selected from the group consisting of drug molecules, metal cations, and cyclodextrin molecules.

13. (previously presented) The composition of Claim 1 or 2 wherein the drug is complexed with a metal cation selected from the group consisting of zinc, calcium, magnesium, bismuth and combinations thereof.

14. (canceled)

15. (previously presented) The composition of Claim 1 or 2, wherein the lipophilic derivative of a drug is a complex comprising the drug and a cyclodextrin.

16. (previously presented) The composition of Claim 1 or 2, wherein the lipophilic derivative of a drug is an ester or amide formed between the drug and a fatty acid.

17. (canceled)

18. (currently amended 1) The composition of Claim ~~17~~ 2 wherein the microparticles ~~emprise consist of drug dispersed in a carrier material selected from the group consisting of fats, fatty substances, waxes, a wax or wax-like material substances and combinations thereof.~~

19. (currently amended) The composition of Claim ~~18~~ 17 wherein the microparticles ~~emprise~~ consist of drug dispersed in a fat or a fatty substance.

20. (currently amended) The composition of Claim ~~47~~ 2 wherein the microparticles ~~comprise~~ consist of a drug dispersed in a carrier material selected from the group consisting of naturally water insoluble proteins, naturally water insoluble polysaccharides, naturally water insoluble lipids and phospholipids, cross-linked water soluble proteins, cross-linked water soluble polysaccharides, cross-linked water soluble cyclodextrins and combinations thereof.

21. (currently amended) The composition of Claim ~~47~~ 1 or 2 wherein the individual microparticles are coated with one or more independent layers, where at least one of the layers is water insoluble and is degraded by enzymes of the human gastrointestinal tract.

22. (cancelled)

23. (original) The composition of Claim 21 wherein at least one of the layers is water-insoluble, organic solvent-insoluble, and degradable by enzymes present in the human gastrointestinal tract.

24. (cancelled)

25. (cancelled)

26. (original) The composition of Claim 21 wherein the enzymatically degradable layer(s) comprise a material selected from the group consisting of naturally water insoluble proteins, naturally water insoluble polysaccharides, naturally water insoluble lipids and phospholipids, cross-linked proteins, cross-linked polysaccharides, and combinations thereof.

27. (currently amended) The composition of Claim 1 or 2 wherein the drug prone to abuse is co-administered with a drug that has no appreciable abuse potential.

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28. (cancelled)

29. (previously presented) The composition of claim 1 or 2 wherein the drug prone to abuse is oxycodone.

30-32. (cancelled)

33. (previously presented) The composition of Claim 2 wherein the drug prone to abuse is selected from the group consisting of 1-phenylcyclohexylamine, 1-piperidinocyclohexanecarbonitrile, alfentanil, alphacetylmethadol, alphaprodine, alprazolam, amobarbital, amphetamine, anileridine, apomorphine, aprobarbital, barbital, barbituric acid derivative, bemidone, benzoylecgonine, benzphetamine, betacetylmethadol, betaprodine, bezitramide, bromazepam, buprenorphine, butabarbital, butalbital, butorphanol, camazepam, cathine, chloral, chlordiazepoxide, clobazam, clonazepam, clorazepate, clotiazepam, cloxazolam, cocaine, codeine, chlorphentermine, delorazepam, dexfenfluramine, dextromoramide, dextropropoxyphen, dezocine, diazepam, diethylpropion, difenoxin, dihydrocodeine, dihydromorphine, dioxaphentyl butyrate, dipanone, diphenoxylate, diprenorphine, ecgonine, enadoline, eptazocine, estazolam, ethoheptazine, ethyl loflazepate, ethylmorphine, etorphine, fempromonex, fencamfamin, fenfluramine, fentanyl, fludiazepam, flunitrazepam, flurazepam, glutethimide, halazepam, haloxazolam, hexalgon, hydrocodone, hydromorphone, isomethadone, hydrocodone, ketamine, ketazolam, ketobemidone, levanone, levoalphacetylmethadol, levomethadone, levomethadyl acetate, levomethorphan, levorphanol, lofentanil, loperamide, loprazolam, lorazepam, lormetazepam, lysergic acid, lysergic acid amide, mazindol, medazepam,

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mefenorex, meperidine, meptazinol, metazocine, methadone, methamphetamine, methohexital, methotrimeprazine, methyl dihydromorphinone, methylphenidate, methylphenobarbital, metopon, morphine, nabilone, nalbuphine, nalbupine, nalorphine, narceine, nefopam, nicomorphine, nimetazepam, nitrazepam, nordiazepam, normethadone, normorphine, oxazepam, oxazolam, oxycodone, oxymorphone, pentazocine, pentobarbital, phenadoxone, phenazocine, phencyclidine, phendimetrazine, phenmetrazine, pheneridine, piminodine, prodilidine, properidine, propoxyphene, racemethorphan, racemorphan, racemoramide, remifentanyl, secobarbital, sufentanil, talbutal, thebaine, thiamylal, thiopental, tramadol, trimeperidine, vinbarbital, allobarbitone, alprazolam, amylobarbitone, aprobarbital, barbital, barbitone, benzphetamine, brallobarbital, bromazepam, brotizolam, buspirone, butalbital, butobarbitone, butorphanol, camazepam, captodiamine, carbromal, carfentanil, carpipramine, cathine, chloral, chloral betaine, chloral hydrate, chloralose, chlordiazepoxide, chlorhexadol, chlormethiazole edisylate, chlormezanone, cinolazepam, clobazam, potassium clorazepate, clotiazepam, cloxazolam, cyclobarbitone, delorazepam, dexfenfluramine, diazepam, diethylpropion, difebarbamate, difenoxin, enciprazine, estazolam, ethyl loflazepate, etizolam, febarbamate, fencamfamin, fenfluramine, fenproporex, fluanisone, fludiazepam, flunitraam, flunitrazepam, flurazepam, flutoprazepam, gepirone, glutethimide, halazepam, haloxazolam, hexobarbitone, ibomal, ipsapirone, ketazolam, loprazolam mesylate, lorazepam, lormetazepam, mazindol, mebutamate, medazepam, mefenorex, mephobarbital, meprobamate, metaclozepam, methaqualone, methohexital, methylpentynol, methylphenobarbital, midazolam, milazolam,

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morphine, nimetazepam, nitrazepam, nordiazepam, oxazepam, oxazolam, paraldehyde, pemoline, pentabarbital, pentazocine, pentobarbital, phencyclidine, phenobarbital, phendimetrazine, phenmetrazine, phenprobamate, phentermine, phenylacetone, pinazepam, pipradol, prazepam, proxibarbal, quazepam, quinalbarbitone, secobarbital, secbutobarbitone, sibutramine, temazepam, tetrazepam, triazolam, triclofos, zalepan, zaleplon, zolazepam, zolpidem, and zopiclone.

34. (currently amended) The composition of Claim 1 or 2 wherein the lipophilic drug and the lipophilic derivative is dissolved in the carrier material in a molten state to result in a uniform dispersion within the carrier material.

35. (currently amended) The composition of Claim 1 or 2 wherein the lipophilic drug and the lipophilic derivative is dissolved in a co-solvent along with a carrier material to result in a uniform dispersion within the carrier material.

36. (previously presented) The composition of Claim 10 wherein the lipophilic counterion is selected from the group consisting of stearic acid, palmitic acid, myristic acid, and mixtures thereof.

37. (currently amended) The composition of Claim 4 9, 10 or 2 36 comprising wherein one or more excipients carrier materials is selected from the group consisting of stearic acid, palmitic acid, beeswax, carnauba wax, hydrogenated oil, and mixtures thereof.

38. (cancelled)

39. (cancelled) .

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40. (currently amended) The composition of claim 1 ~~17~~ or ~~39~~ 2, wherein the individual microparticles are further formulated into a tablet or capsule for oral administration.

41. (new) The composition of claim 37 wherein the drug prone to abuse is selected from the group consisting of oxycodone, oxymorphone, hydrocodone, hydromorphone, morphine, tramadol, methylphenidate, and amphetamine.